



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,165	07/21/2006	Paul B Savage	0179689010-US00	5240

23510 7590 01/09/2008
MICHAEL BEST & FRIEDRICH LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
----------	--------------

1623

MAIL DATE	DELIVERY MODE
-----------	---------------

01/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,165	Applicant(s) SAVAGE ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 18, 19, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 18-19 and 24-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 10/22/2007 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 14-17 and 20-23 have been canceled.
2. Remarks drawn to objections and rejections under 35 USC 102 and 103.

Claims 1-13, 18-19 and 24-25 are pending in the case.

Specification

The objection to the abstract advanced in the previous action is being maintained.

Applicants have not responded to this objection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of Claims 1-2, 5 and 18-19 under 35 U.S.C. 102(a) as being anticipated by Savage et al (Organic Letters, 2002, 4(8), 1267-70; document AD in the IDS of 3/3/2006) has been overcome by filing of a Declaration under 35 CFR 1.132 establishing that Dr. Savage, Luc Teyton and Albert Bedelac listed on the Savage reference invented the presently claimed subject matter and that the remaining four authors listed in the reference did not make an inventive contribution and hence the Savage reference is not “by another” as required under 102(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 18-19 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al (Organic Letters, 2002, 4(8), 1267-70; document AD in the IDS of 3/3/2006) in view of Kawano et al (Science, 1997, 278, 1626-29); document cited in IDS of 5/25/2007) has been overcome in view of the Declaration as explained above.

The following new art rejection is made of record.

Claims 1-13, 18-19 and 24-25 are rejected under are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al (US 7273852; priority of provisional application Jan.13, 2002) newly cited in view of Defrees et al (US 5,604,207), Sinay et al (Bioorganic and Medicinal Chemistry, 1998, 6, 1337-46) newly cited and Kawano et al (Science, 1997, 278, 1626-29); document cited in IDS of 5/25/2007).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Tsuji et al, drawn to glycolipids, teaches compounds of formula (I) that has the structural features as instantly claimed, wherein R3 or R4 can be an OH, X is substituted amine, Q1-Q3 are alkyls and X' and X'' can be absent and its compositions (col. 12, line 51 through col. 12, line 24). The only difference is that the compound of Tsuji of formula (I) is a C-sugar, whereas the instant compound in claim 1 is an O-sugar (col. 6, lines 5-45). But Tsuji et al also teach O-sugars with structural features as instantly claimed (col. 5, structure labeled KRN 7000), which is taught to be biologically active too.

Kawano et al, drawn to activation of NKT cells, teach that fatty acyl chains in combination with galactosyl moiety (GalCer) are important for selective activation of NKT cells and it is these cells that kill target tumor cells by an NK like mechanism and inhibit tumor growth and metastasis (page 1628, left column, last paragraph and middle column, first full paragraph).

However, Tsuji and Kawano do not teach a method of synthesis as instantly claimed.

Sinay, drawn to polysaccharide synthesis teaches the conversion of an azide group on the sugar moiety to an amino group via reduction (page 1340, Scheme 6, conversion of structure 28

to structure 29). This is same as step (i) in instant claim 24 for conversion of compound (III) to compound (IV). Defrees, aminosugar analogs teaches compound 51 (col. 87-88, Table 4) that has a benzenesulfonyl group attached to the nitrogen of the amino group. At col. 66, Example 2, a very similar alkoylation of amino nitrogen is taught using 2,5-dichlorobenzoyl chloride. One of skill in the art will recognize from these two examples that the sulfonylation of compound 51 of Defrees can be performed with the corresponding benzenesulfonyl chloride and also the same reaction can be performed on a similar polysaccharide or a monosaccharide as instantly claimed using a sulfonyl halide (RSO_2Cl) as instantly claimed. Thus, the steps need for the conversions as instantly claimed are seen to be taught in the prior art using analogous compounds and this can be extended to the compounds as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compounds of formula I, their compositions and use them in a method to stimulate NKT cells and make the said compounds via the process as instantly claimed since such is seen to be taught in the prior art using closely analogous compounds. It is well within the skill level of the artisan to apply the same conversion steps to the compound as instantly claimed in claims 24-25.

One of skill in the art would be motivated to make the compounds and their compositions as instantly claimed since closely analogous compound have been shown to be good stimulators of NKT cells, which are known to inhibit tumor growth and metastasis. Hence one of skill in the art would look for structurally related compounds that are more potent inhibitors. Obviousness based on similarity of structure and function entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar

properties. Where prior art compound essentially brackets the claimed compounds and are well known active agents for the intended purpose, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new anticancer/antitumor agents. In re Payne, 606 F. 2d 303, 203, USPQ, 245, 254-55 (C.C.P.A. 1979).

Conclusion

Claims 1-13, 18-19 and 24-25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

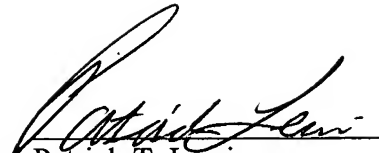
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:
10/550,165
Art Unit: 1623

Page 7

GK



Patrick T. Lewis
Primary Patent Examiner
Art Unit 1623